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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,923	02/11/2004	Michael J. Campbell	65466US-CIP2(53472)	2359
21874	7590	11/22/2006	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			SCHELL, LAURA C	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/776,923

Applicant(s)

CAMPBELL ET AL.

Examiner

Laura C. Schell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/27/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the details the reference numbers refer to in the hand-drawn Figures are difficult to see. Furthermore, when this case is passed to allowance, formal drawings will be required before it can be allowed. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "trocar" and the "surgical instrument through a lumen in the trocar" must be shown or the feature(s) canceled from the claim(s). It is noted that in Figs. 6 and 7 applicant has a surgical instrument within a lumen of a *cannula*, but not a trocar. The only figure which shows surgical instruments within a trocar is Fig. 5, however, this figure does not match up with claim 9, as the pressurized gas in Fig. 5 flows into the trocar and not the surgical instrument. It is suggested that Applicant change "cannula" in Figs. 6 and 7 to "trocar" and change the corresponding references within the specification as well. No new matter should be entered.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "60" has been used to designate both the surgical

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instrument as well as the lumen surrounding the surgical instrument as it appears in Fig. 6.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "72" in Fig. 7 has been used to designate both the valve as well as the operative instrument.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-11, 14 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Mantell et al. (US Patent No. 6,905,489). Mantell discloses the method of maintaining an operative pneumoperitoneum in a patient undergoing a surgical

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procedure comprising the steps of: introducing a trocar through a portion of an abdominal wall of a patient (Figs. 5 and 6, element 86; col. 7, lines 11-13 and 17-18); introducing a surgical instrument through a lumen in the trocar (Fig. 6, 88; col. 4, lines 48-49); introducing a pressurized gas from a controlled pressure source into the surgical instrument (Fig. 6, 88; col. 6, lines col. 6, lines 52-65); and directing the pressurized gas from the surgical instrument into the patient through a passageway between the surgical instrument and a wall of the lumen in the trocar (Fig. 6 discloses that the gas can flow from inside 88 through opening 94 into the passageway between 88 and 86).

In reference to claim 10, Mantell discloses the step of sealing the passageway between the surgical instrument and the wall of the lumen in the trocar to block the escape of gas introduced into the patient (Fig. 2, 48; also see col. 8, lines 1-5).

In reference to claim 11, Mantell discloses that the step of directing pressurized gas from the surgical instrument into the patient through a passageway between the surgical instrument and a wall of the lumen in the trocar involves directing a flow of pressurized gas through at least one port in a wall portion of the surgical instrument (Fig. 6, 94; col. 6, lines 60-65).

In reference to claim 14, Mantell discloses that the step of sealing the passageway between the surgical instrument and the wall of the lumen in the trocar includes the step of arranging a removable valve at a proximal end portion of the trocar (col. 8, lines 1-5).

In reference to claim 21, Mantell discloses that the step of directing the pressurized gas from the surgical instrument into the patient involves directing a flow of

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pressurized gas into the lumen of the trocar at a location distal to any valve arrangement within the trocar (Fig. 6 discloses that the flow of gas exits at port 94, which is clearly distal of valve 48 as well as any valve within 54).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mantell et al. (US Patent No. 6,905,489) in view of Trudel et al. (US Patent No. 6,544,210). Mantell discloses the method substantially as claimed except for introducing a second cannula for an additional access port for surgical instruments. Trudel, however, discloses the step of introducing a first cannula into an abdominal wall portion of the patient (col. 3, line 61 through col. 4, line 27); and introducing at least one operative surgical instrument through the first cannula to permit simultaneous operative function with the trocar (see Fig. 1, wherein the cannula is element 32, the instrument is 44 and

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the trocar used for insufflation is 30, also wherein the definition of "cannula" according to the Merriam-Webster's Online Dictionary is "a small tube for insertion into a body cavity or into a duct or vessel" (<http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=cannula>) see also col. 4, lines 1-6; col. 4, lines 17-22; col. 4, lines 22-27). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Mantel with the second cannula, as taught by Trudel, in order to provide an additional access port for additional surgical instruments, while still being connected with the insufflating trocar to maintain the pneumoperitoneum.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mantel et al (US Patent No. 6,905,489) in view of Trudel et al. (US Patent No. 6,544,210) and further in view of Goodson et al. (US Patent No. 4,735,603). Mantel in view of Trudel discloses the method substantially as claimed except for the insertion of a third cannula for monitoring the pneumoperitoneum. Goodson, however, discloses using a third cannula (col. 3, lines 46-55) wherein the third cannula comprises a pressure sensor in order to sense the pressure in the pneumoperitoneum and helps maintain a proper pressure (see abstract and col. 2, lines 16-28). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Mantel in view of Trudel by using one of the cannulas as a means to monitor the pneumoperitoneum in order to maintain the needed pressure within the abdomen for a successful surgery (col. 2, lines 29-46).

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mantel et al. (US Patent No. 6,905,489) in view of Goodson et al. (US Patent 4,735,603).

Mantel discloses a method of maintaining an operative pneumoperitoneum in a patient undergoing a surgical procedure comprising: introducing a trocar through a portion of an abdominal wall of a patient at a first site (Figs. 5 and 6, element 86; col. 7, lines 11-13 and 17-18); introducing at least one surgical instrument through a lumen in the trocar (Fig. 6, 88; col. 4, lines 48-49); introducing a pressurized gas from a controlled pressure source into the at least one surgical instrument (Fig. 6, 88; col. 6, lines col. 6, lines 52-65); directing the pressurized gas from the at least one surgical instrument into the patient through a gas passageway between the at least one surgical instrument and a wall of the lumen in the trocar (Fig. 6 discloses that the gas can flow from inside 88 through opening 94 into the passageway between 88 and 86) and sealing the passageway between the at least one surgical instrument and the wall of the lumen in the trocar (Fig. 2, 48; also see col. 8, lines 1-5). Mantel, however, does not disclose inserting an additional cannula for monitoring the pressure within the abdomen.

Goodson, however, discloses introducing a cannula through the abdominal wall of the patient at a second site (col. 3, lines 46-55); monitoring gas pressure within the abdomen of the patient through the cannula and controlling gas pressure within the abdomen of the patient based upon feedback from the cannula (see abstract and col. 2, lines 16-28). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Mantel by using one of the cannulas as a

means to monitor the pneumoperitoneum in order to maintain the needed pressure within the abdomen for a successful surgery (col. 2, lines 29-46).

In reference to claim 17, Mantel discloses the method substantially as claimed except for the cannula being in operative communication with the trocar. Goodson, however, discloses that the trocar and the cannula are arranged in operative communication with one another to controllably balance pressurized gas introduced into the patient (see abstract and col. 2, lines 16-28). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Mantel with the communication between the cannula and the trocar, as taught by Goodson, in order to provide a means of sensing and controlling the pressure within the abdomen and replacing any escaped gas.

In reference to claim 18, Mantel discloses that the trocar has a plurality of surgical instruments extending therethrough simultaneously (Fig. 6 discloses a cannula (88) and an obturator (38) extending through the trocar (78) simultaneously).

In reference to claim 19, Mantel discloses the method substantially as claimed except for an additional cannula with an open bore. Goodson, however, discloses an additional cannula (col. 3, lines 46-55) with an open bore (Fig. 6, 55 discloses that there is an open bore at the top of the cannula to permit insertion of a laser) extending therethrough to permit operative instruments therethrough. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Mantel with the additional cannula with an open bore, as taught by Goodson,

in order to provide a means for additional access to the abdomen with other surgical instruments.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mantel (6,905,489) in view of Goodson et al. (US Patent No. 4,735,603) and further in view of Garrison et al. (US Patent No. 6,645,197). Mantel in view of Goodson discloses the method substantially as claimed except for forming a pressurized gas seal about an instrument. Garrison, however, discloses sealing a passageway between the surgical instrument and the wall of the lumen in the trocar by forming a pressurized gas seal about the instrument within the passageway (Figs. 5-8, 14 and 15 disclose the trocar (2) with a flow of pressurized gas which seals the passage between the instrument (Fig. 8, 22) and the trocar (2); see abstract). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Mantel in view of Goodson, with the step of forming a pressurized gas seal about the instrument, as taught by Garrison, in order to allow the use of multiple types of instruments in the trocar without having to use mechanical seals, which are not capable of sealing every possible size and shape tool which will be used.

Claims 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mantel (US Patent No. 6,905,489) in view of Garrison et al. (US Patent No. 6,645,197). Mantel discloses the method substantially as claimed except for forming a pressurized gas seal about an instrument. Garrison, however, discloses sealing a passageway between the surgical instrument and the wall of the lumen in the trocar by forming a pressurized gas seal about the instrument within the passageway (Figs. 5-8, 14 and 15 disclose the

trocar (2) with a flow of pressurized gas which seals the passage between the instrument (Fig. 8, 22) and the trocar (2); see abstract). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Mantel, with the step of forming a pressurized gas seal about the instrument, as taught by Garrison, in order to allow the use of multiple types of instruments in the trocar without having to use mechanical seals, which are not capable of sealing every possible size and shape tool which will be used.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

